69

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 August 2001 (30.08.2001)

PCT

(10) International Publication Number
WO 01/62327 A1

(51) International Patent Classification[7]: A61M 25/00

(21) International Application Number: PCT/US01/02010

(22) International Filing Date: 22 January 2001 (22.01.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/510,033 22 February 2000 (22.02.2000) US

(71) Applicant: **SCIMED LIFE SYSTEMS, INC.** [US/US]; One SciMed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventors: **WANG, Lixiao**; 12822 - 86th Place North, Maple Grove, MN 55369 (US). **CHEN, John, Jianhua**; 4725 Terraceview Lane, Plymouth, MN 55446 (US).

(74) Agent: **GRAD, Jonathan**; Vidas, Arrett & Steinkruas, 6109 Blue Circle Drive, Suite 2000, Minnetonka, MN 55343-9185 (US).

(81) Designated States *(national)*: CA, JP.

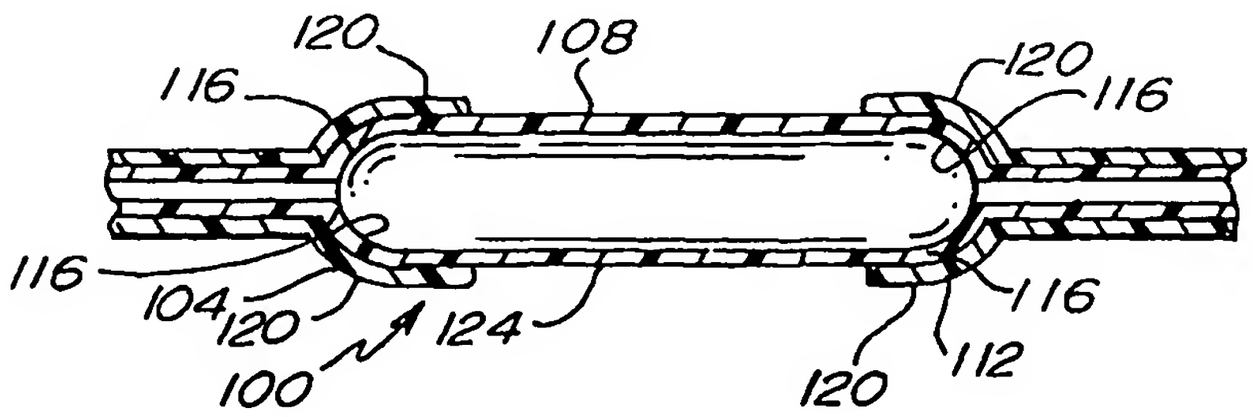
(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/62327 A1

(54) Title: STENT DELIVERY BALLOON WITH STENT SECUREMENT MEANS



(57) Abstract: A stent delivery balloon structure is formed by molding at a desired pressure, temperature and tension a medical balloon with a tube disposed thereabout and subsequently removing one or more layers of material from the body portion of the thus formed medical balloon structure.

STENT DELIVERY BALLOON WITH STENT SECUREMENT MEANS

BACKGROUND OF THE INVENTION

In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through a vessel and advanced therein until the distal end of the catheter is at a desired location in the vasculature. A guidewire and a dilatation catheter having a balloon on the distal end thereof are introduced through the guiding catheter with the guidewire sliding through the dilatation catheter. The guidewire is first advanced out of the guiding catheter into the patient's coronary vasculature and the dilatation catheter is advanced over the previously advanced guidewire until the dilatation balloon is properly positioned across the lesion. Once in position across the lesion, the flexible, expandable, preformed balloon is inflated to a predetermined size with a liquid or gas at relatively high pressures, such as greater than about four atmospheres, to radially compress the arthrosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile so that the dilatation catheter may be withdrawn from the patients vasculature and blood flow resumed through the dilated artery.

In angioplasty procedures of the kind described above, there may be restenosis of the artery, which either necessitates another angioplasty procedure, a surgical by-pass operation, or some method of repairing or strengthening the area. To help prevent restenosis and strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency inside the artery at the lesion. The intravascular prosthesis or stent is expanded to a larger diameter for placement in the vasculature, often by the balloon portion of the catheter. Examples of balloon expandable stents are provided in U.S. 5,807,404 and U.S. 5,868,781. The stent is delivered on a stent delivery catheter. Examples of stent delivery catheters include those disclosed in US 5,944,726, US 5,772,669 and U.S. Pat. No. 4,733,665.

During the delivery of a balloon expandable stent to a desired bodily location, the stent may move relative to the balloon resulting in a non-uniform expansion of the stent and rendering difficult the accurate deployment of the stent. It is,

therefore, desirable, in delivering a balloon expandable stent to a desired bodily location, to secure the stent to the balloon prior to expansion of the balloon and stent. A number of stent securement methods and devices have been proposed. U.S. 5,944,726 discloses several stent securement devices including mounting bodies. U.S. 4,950,227 discloses the use of sleeves disposed over a portion of the proximal and distal ends of a stent.

For the purpose of this disclosure, all US patents and patent applications and all other publications referenced herein are incorporated herein by reference in their entirety.

Without limiting the scope of the invention in any way, the invention is briefly summarized below.

BRIEF SUMMARY OF THE INVENTION

The present invention is directed in one embodiment to a method of forming a medical balloon structure. In accordance with the inventive method, a tube is provided and an inner structure selected from the group consisting of medical balloons and medical balloon tubes is also provided. The tube is disposed about the inner structure. The tube and inner structure are then placed in a balloon mold and a predetermined pressure, tension and temperature are applied to the tube and inner structure so as to form a medical balloon structure. The thus formed medical balloon structure includes a proximal cone portion, a body portion and a distal portion and has an outer wall formed from the tube and an inner wall formed from the inner structure. At least a portion of the outer wall is removed from the body portion of the medical balloon structure. Desirably, the entirety of the outer wall in the region of the body portion is removed.

The invention is also directed to a method of forming medical balloon structures comprising the steps of providing an inner structure selected from the group consisting of medical balloons and medical balloon tubes and a plurality of tubes disposed in layers about the inner structure and placing the inner structure and tubes in a mold. The inner structure and plurality of tubes are then molded at a predetermined pressure, tension and temperature so as to form a medical balloon structure having proximal and distal cone portions and a body portion. Subsequent to molding, a desired

number of layers of tube are removed from the body portion of the medical balloon structure.

The invention is also directed to medical balloons formed in accordance with the inventive methods. In particular, the invention is directed to a medical balloon structure having been formed of an inner structure selected from the group consisting of medical balloons and medical balloon tubes and a tube disposed thereabout. The inner structure and tube are molded to form a medical balloon structure having proximal and distal cone portions and a body portion. At this stage, the tube forms the outer wall of the medical balloon structure and the inner structure forms the inner wall of the medical balloon structure. A portion of the outer wall, desirably, the entirety of the outer wall, is then removed from the body portion of the medical balloon structure to form the inventive medical balloon structure.

The invention is also directed to medical balloon structures formed from an inner structure selected from the group consisting of medical balloons and medical balloon tubes and a plurality of tubes disposed in layers about the inner structure. The inner structure and plurality of tubes are molded so as to form a medical balloon structure having proximal and distal cone portions and a body portion. Subsequent to molding, a desired number of layers of tube are removed from the body portion of the medical balloon structure.

In yet another embodiment, the invention is directed to a medical balloon structure comprising a proximal cone portion, a distal cone portion and a body portion. The proximal cone portion, distal cone portion and body portion each have a number of layers of material. At least a portion of the body portion has fewer layers of material than at least one of the proximal and distal cones.

The invention is further directed to catheters comprising the inventive medical balloons. One such catheter is a stent delivery catheter employing an inventive balloon. Desirably, at least one outer layer of the proximal and distal cone sections will be moved toward one another and reside over portions of the proximal and distal ends of the stent.

In another aspect, the invention is directed to a method for fastening a stent to a catheter in a manner suitable for introduction, and later release, of the stent to a body cavity. The method includes the steps of (a) providing a catheter having an

inventive medical balloon structure as disclosed above disposed about a distal portion thereof; (b) providing a stent having a contracted and an expanded condition; (c) disposing the stent about the body portion of the medical balloon structure; and (d) pulling a portion of the proximal and distal cones toward one another so that a portion of the proximal cone is disposed over a proximal portion of the stent and a portion of the distal cone is disposed over of a distal portion of the stent thereby fixing the stent to the catheter when the stent and medical balloon structure are in their contracted state or condition.

In yet another aspect of the invention, the invention features a method for positioning a stent within a body cavity, including the steps of (a) providing a stent delivery system with an inventive medical balloon structure and stent secured thereto; (b) introducing the stent delivery system into the body cavity; (c) causing the medical balloon structure to expand and thereby simultaneously expanding the stent and causing the portions of the cone section which overlie the proximal and distal portions of the stent to be released from their position overlying the stent, at least partially contracting the catheter, and (d) removing the catheter from the body cavity by axially pulling the catheter from the body cavity.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

Figure 1 shows a side elevational view of a medical balloon structure prior to removal of materials from the body portion.

Figure 2 shows a side elevational view of the medical balloon structure of Fig. 1 following removal of material from the body portion.

Figures 3 shows a perspective view of the medical balloon structure shown in Fig. 2.

Figure 4 shows a side elevational view of a portion of an inventive medical balloon structure with a stent disposed thereon, the balloon structure mounted on a stent delivery catheter.

DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This

description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

For the purposes of this disclosure, the term stent refers to stents, stent-grafts, grafts and other endoluminal prostheses.

In one embodiment, the invention is directed to a method of forming an inventive medical balloon structure. In accordance with the method, an inner structure in the form of a medical balloon is provided and a tube is provided. The tube is disposed about the balloon and the tube and medical balloon placed in a balloon mold. In accordance with well known balloon production methodology, a predetermined pressure, tension and temperature are applied to the tube and balloon in the mold so as to form a medical balloon structure. The resulting medical balloon structure, shown generally at 100 in Fig. 1, includes a proximal cone portion 104, a body portion 108 and a distal portion 112. An outer wall 103 of the medical balloon structure is formed from the tube and an inner wall 105 of the balloon structure is formed from the medical balloon. As shown in Figs. 2 and 3, at least a portion of the outer wall is removed from the body portion 108 of the medical balloon structure. The entire portion of the outer wall may be removed from body portion 108 of balloon structure 100 but desirably, a short length of outer wall will remain adjacent to the cones, as shown in Fig. 2. The exact amount of outer wall remaining in the body portion adjacent to the cones will depend on the intended use of the balloon.

In another embodiment of the invention, an inner structure in the form of a medical balloon tube is provided and a second tube is provided. The tube is disposed about the balloon tube and the tube and medical balloon tube placed in a balloon mold. In accordance with well known balloon production methodology, a predetermined pressure, tension and temperature are applied to the tube and balloon tube in the mold so as to form a medical balloon structure. Subsequent to molding, a desired amount of balloon material is removed from the body portion of the medical balloon structure.

The invention is also directed to a method of forming a medical balloon structure comprising the steps of providing a medical balloon or a medical balloon tube and a plurality of tubes disposed in layers about the medical balloon or medical balloon tube and placing the balloon (or balloon tube) and tubes in a mold. The medical balloon (or balloon tube) and plurality of tubes are then molded at a predetermined pressure,

tension and temperature so as to form a medical balloon structure having proximal and distal cone portions and a body portion. Subsequent to molding, a desired number of layers of tube are removed from the body portion of the medical balloon structure.

The materials removal step may be accomplished using any of a number of material removal techniques include mechanical, chemical or laser. Mechanical means for removal of the outer layer(s) include mechanical trimming, skiving and grinding. A suitable grinding process is described in commonly assigned US Application No. 09/401618 filed September 22, 1999. The outer layer(s) may also be removed by masking suitable portions of the balloon and chemically etching the balloon or by laser ablation of the layer(s) from the body portion. A suitable process for laser ablation is disclosed in US 5,826,588 to Forman.

The invention is also directed to inventive balloons formed in accordance with the inventive methods disclosed herein.

The invention is also directed to a medical balloon structure whose body portion and cone portions are comprised of a predetermined number of layers of material. The number of layers of material in the cone sections differs from the number of layers of material in the body section. Desirably, the number of layers of material in the cone section will exceed the number of layers of material in the body portion of the balloon structure.

In one embodiment of the invention, as shown in Fig. 2, a medical balloon structure shown generally at 100 includes a proximal cone portion 104, a body portion 108 and a distal cone portion 112. Proximal cone portion 104 and distal cone portion 108 are each formed of two layers of material. Each cone portion has an inner wall 116 and an outer wall 120. Body portion 112 consists of a single layer of material 124.

The proximal and distal cone sections may comprise additional layers, as may the body portion, as long as the number of layers of the cones exceeds the number of layers of the body section.

In yet another embodiment, the invention is directed to a medical balloon structure comprising a proximal cone portion, a distal cone portion and a body portion. The proximal cone portion, distal cone portion and body portion each have a number of layers of material. At least a portion of the body portion has fewer layers of material

than at least one of the proximal and distal cones. The proximal and distal cone portions may have a like number of layers or a different number of layers. Where the proximal and distal cone portions have a different number of layers, the difference in the number of layers may be achieved by removing layers of material from at least one of the proximal and cone portions. One such balloon may have a few number of layers of material in the proximal cone portion to allow for improved trackability of the balloon.

The inventive balloons may be used for a variety of purposes. They are especially useful as expansion means in stent delivery catheters. A medical balloon structure for use in stent delivery is shown in Fig. 4. Medical balloon structure 100, similar to that shown in Fig. 2, is mounted on the distal end of catheter 132. Although not shown, catheter 132 includes an inflation lumen in fluid communication with medical balloon 100. Stent 128 is disposed about body portion 112 of medical balloon structure 100. Desirably, as shown in Fig. 4, outer walls 120 of the proximal 104 and distal cone portions 108 are pulled toward one another to cover a portion of the proximal and distal ends of stent 128 and aid in stent retention.

Where the balloon structure is formed of a plurality of tubes, it is desirable to remove a sufficient number of layers from the body portion so as to form a recessed portion in which the stent may reside.

More generally, in the case of a balloon for expansion of a stent, regardless of how many layers of material are used in the formation of the inventive balloon, sufficient material should be removed so as to form a recessed portion in which the stent may reside. Desirably, sufficient balloon material should be removed so that portions of the balloon adjacent to the recess will extend to at least 50% and more desirably 75% of the height of a stent (unexpanded) which is disposed in the recess. Even more desirably, sufficient balloon material should be removed so that the portions of the balloon adjacent to the recess will extend above a stent (unexpanded) disposed in the recess. To that end, the inventive balloons may be made prepared by removing a predetermined amount of material from the body portion of the stent, the amount of material to be determined on the basis of the inner and outer diameters of the unexpanded stent to be disposed in the thus formed recess.

Also, in the case of a balloon for expansion of a stent, the axial length of the recess which is formed by removal of material from the body portion of the balloon

should correspond to the length of the stent to be disposed in the recess or be slightly longer.

The invention is further directed to catheters comprising the inventive balloons disclosed herein. In one embodiment, the invention is directed to a stent delivery catheter comprising an inventive balloon disposed thereon and a stent disposed on the balloon. Desirably, the proximal and distal portions of the stent will have a portion of the proximal and distal cones pulled thereover, as shown in Fig. 4, to aid in stent retention. The inventive balloons may be used in conjunction with virtually any stent delivery catheter configured for balloon expansion of the stent.

In another aspect, the invention is directed to a method for fastening a stent to a catheter in a manner suitable for introduction, and later release, of the stent to a body cavity. The method includes the steps of (a) providing a catheter having an inventive medical balloon structure as disclosed above disposed about a distal portion thereof; (b) providing a stent having a contracted and an expanded condition; (c) disposing the stent about the body portion of the medical balloon structure; and (d) pulling a portion of the proximal and distal cones toward one another so that a portion of the proximal cone is disposed over a proximal portion of the stent and a portion of the distal cone is disposed over of a distal portion of the stent thereby fixing the stent to the catheter when the stent and medical balloon structure are in their contracted state or condition.

In yet another aspect of the invention, the invention features a method for positioning a stent within a body cavity, including the steps of (a) providing a stent delivery system with an inventive medical balloon structure and stent secured thereto, as described above; (b) introducing the stent delivery system into the body cavity; (c) causing the medical balloon structure to expand and thereby simultaneously expanding the stent and causing the portions of the cone section which overlie the proximal and distal portions of the stent to be released from their position overlying the stent, at least partially contracting the catheter, and (d) removing the catheter from the body cavity by axially pulling the catheter from the body cavity.

The medical balloon and tubes for use in the practice of the inventive method is desirably formed from a material selected from the group consisting of non-compliant balloon materials, semi-compliant balloon materials and combinations

thereof. Suitable non-compliant and semi-compliant materials include polyethyleneterephthalate (PET), high density polyethylene, polyamides, polycarbonates, Nylon, polyurethanes, polyvinyl chloride, ethylene-vinyl acetate copolymers, and mixtures and combinations thereof. Other suitable materials include thermoplastic elastomers i.e. block copolymers; copolymers and terpolymers of ethylene; homopolymers, copolymers and terpolymers of propylene; ethylene α-olefins; polyesters; vinyl copolymers; ionomer materials and so forth. More specifically, materials such as Selar®, polyether-polyester block copolymers (i.e. Hytrel® from DuPont or Arnitel® from DSM, Netherlands), Pebax®(polyether block amide copolymers), Surlyn®, polytetrafluoroethylene, polyetherurethanes, polyesterurethanes, polyurethane ureas, polyurethane siloxane block copolymers, silicone polycarbonate copolymers, acrylonitrile-butadiene-styrene copolymers; polyphenylene sulfides; copolyesters or other similar extrudable thermoplastic, polymeric materials, or composites thereof may be utilized in the present invention.

Desirably, the inventive medical balloon structure will have a soft outer layer. Also desirably, the medical balloon or medical balloon tube will be made of a material which is harder than the tubing material. To that end, a medical balloon or medical balloon tube may be inserted into a soft and lower durometer thermoplastic elastomer tubing in order to form the inventive medical balloon structure.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

In addition to the specific embodiments claimed below, the invention is also directed to other embodiments having any other possible combination of the dependent features claimed below. The particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim

which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below (e.g. claim 3 may be taken as alternatively dependent from claim 2; claim 4 may be taken as alternatively dependent on claim 2, or on claim 3; claim 6 may be taken as alternatively dependent from claim 5; etc.).

The above disclosure is intended to be illustrative and not exhaustive. The description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

The contents of parent U.S. application No. 09/510,033 filed February 22, 2000 are incorporated herein by reference in their entirety.

CLAIMS:

1. A method of forming a medical balloon structure comprising the steps of:

providing an inner structure selected from the group consisting of medical balloons and medical balloon tubes;

providing at least one tube;

disposing the tube about the inner structure;

placing the tube disposed about the inner structure in a balloon mold;

applying a predetermined pressure, tension and temperature to the tube and inner structure to form a medical balloon structure, the medical balloon structure including a proximal cone portion, a body portion and a distal portion, the medical balloon structure having an outer wall formed from the tube and an inner wall formed from the inner structure;

removing the medical balloon structure from the mold;

removing at least a portion of the outer wall from the body portion of the medical balloon structure.

2. The method of claim 1 wherein the entirety of the outer wall is removed from the body portion of the balloon structure.

3. The method of claim 1 wherein the inner structure is formed of a material selected from the group consisting of non-compliant balloon materials, semi-compliant balloon materials and combinations thereof.

4. The method of claim 1 wherein the tube is formed of a thermoplastic elastomer.

5. The method of claim 1 wherein the inner structure is made of a material which is harder than the tubing material.

6. The method of claim 1 wherein:

the entirety of the outer wall is removed from the body portion of the balloon structure,

the inner structure is formed of a material selected from the group consisting of non-compliant balloon materials, semi-compliant balloon materials and combinations thereof,

the tube is formed of a thermoplastic elastomer, and

the inner structure is made of a material which is harder than the tubing material.

7. The method of claim 1 wherein a plurality of tubes are disposed in layers about the inner structure and one or more layers of tube are removed from the body portion of the medical balloon structure.

8. A balloon structure made in accordance with the method of claim 1.

9. The balloon structure of claim 8 mounted on a catheter.

10. A stent delivery catheter comprising a medical balloon structure formed in accordance with claim 6 and a stent mounted on the balloon structure.

11. The stent delivery catheter of claim 10 wherein the medical balloon structure includes a proximal cone portion having an inner wall and an outer wall, a distal cone portion having an inner wall and an outer wall and a body portion consisting of an inner wall and the stent is disposed about the body portion.

12. The stent delivery catheter of claim 11 wherein at least the outer walls of the proximal and distal cone sections are pulled toward one another so as to cover a portion of the proximal and distal ends of the stent.

13. The medical balloon structure of claim 8 wherein the inner structure is a medical balloon.

14. The medical balloon structure of claim 8 wherein the inner structure is a medical balloon tube.

15. A medical balloon structure comprising:

a proximal cone portion;

a distal cone portion;

a body portion;

the proximal cone portion having at least two layers of material;

the distal cone portion having a number of layers of material; and

the body portion having a number of layers of material,

wherein at least a portion of the body portion has fewer layers of material than at least one of the proximal and distal cones.

16. The medical balloon structure of claim 15 wherein the proximal and distal cone portions are formed of the same number of layers of material.

17. The medical balloon structure of claim 16, the proximal and distal cone sections having an outer wall and an inner wall, the body portion having only an inner wall, wherein

the outer wall of the proximal cone portion and the outer wall of the distal cone portion were formed of a single tube,

the inner wall of the medical balloon structure was formed of a an inner structure selected from the group consisting of medical balloons and medical balloon tubes,

the inner structure and tube were molded, at least a portion of the tube overlying the body portion having been removed subsequent to molding.

18. The medical balloon structure of claim 16 wherein the proximal and distal cone outer walls are made of a material softer than the material from which the inner structure is made.

19. The medical balloon structure of claim 16 wherein the inner structure is formed of a material selected from the group consisting of compliant balloon materials, semi-compliant balloon materials and combinations thereof.

20. The medical balloon structure of claim 16 wherein the tube is formed of a thermoplastic elastomer.

21. The medical balloon structure of claim 16 wherein:

the proximal and distal cone outer walls are made of a material softer than the material from which the inner structure is made,

the inner structure is formed of a material selected from the group consisting of compliant balloon materials, semi-compliant balloon materials and combinations thereof, and

the tube is formed of a thermoplastic elastomer.

22. A catheter including a medical balloon structure as in claim 16 disposed thereon.

23. A catheter including a medical balloon structure as in claim 21 disposed thereon.

24. A stent delivery catheter including a medical balloon structure as in claim 21 disposed thereon and a stent disposed about the body portion of the balloon structure.

25. The medical balloon structure of claim 17 wherein the inner structure is a medical balloon.

26. The medical balloon structure of claim 17 wherein the inner structure is a medical balloon tube.

27. The medical balloon structure of claim 16 wherein the portion of the body portion having fewer layers of material than the proximal and distal cones forms a recess sized to receive an unexpanded stent.

28. The medical balloon structure of claim 27 with a stent received in the recess.

29. A method of forming a medical balloon comprising the steps of:

providing a medical balloon structure having a body portion, the structure comprising a plurality of layers including an outer wall;

removing at least a portion of the outer wall from the body portion of the medical balloon structure.

30. The method of claim 29 wherein the entirety of the outer wall is removed from the body portion of the medical balloon structure.

1/1

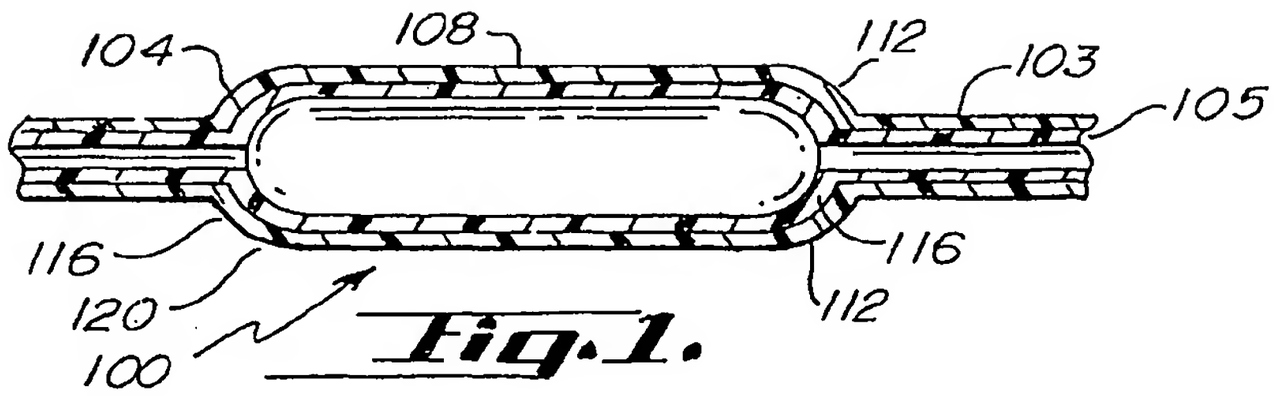


Fig. 1.

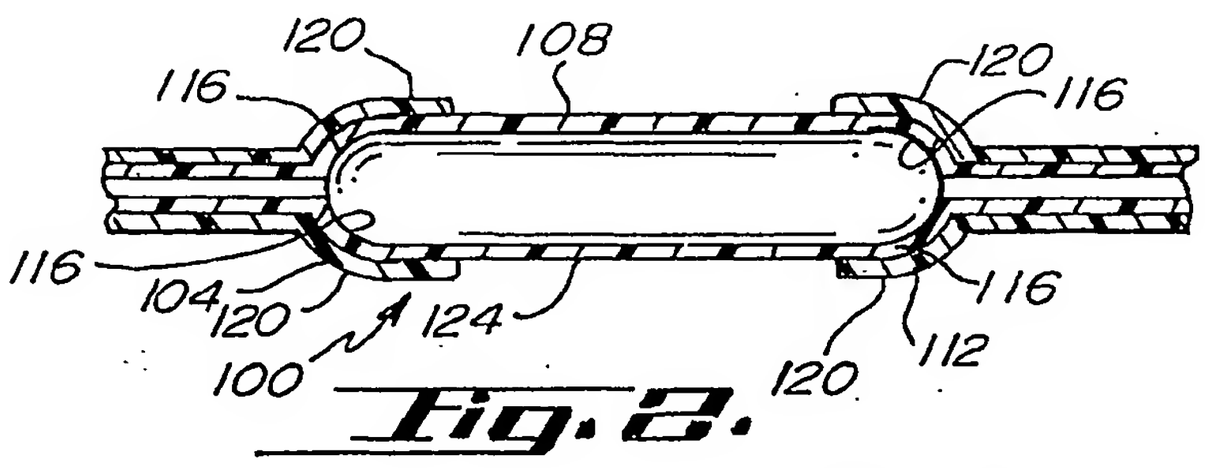


Fig. 2.

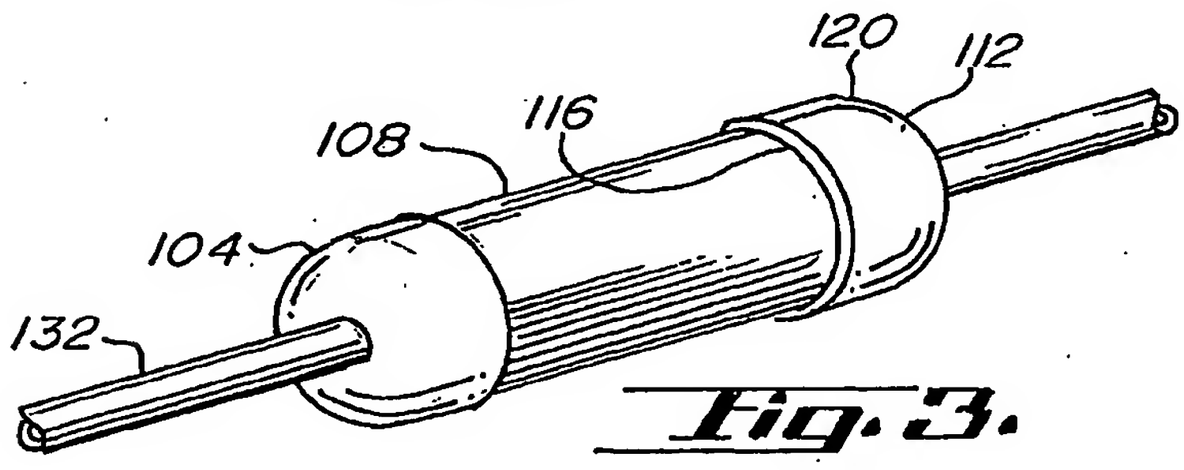


Fig. 3.

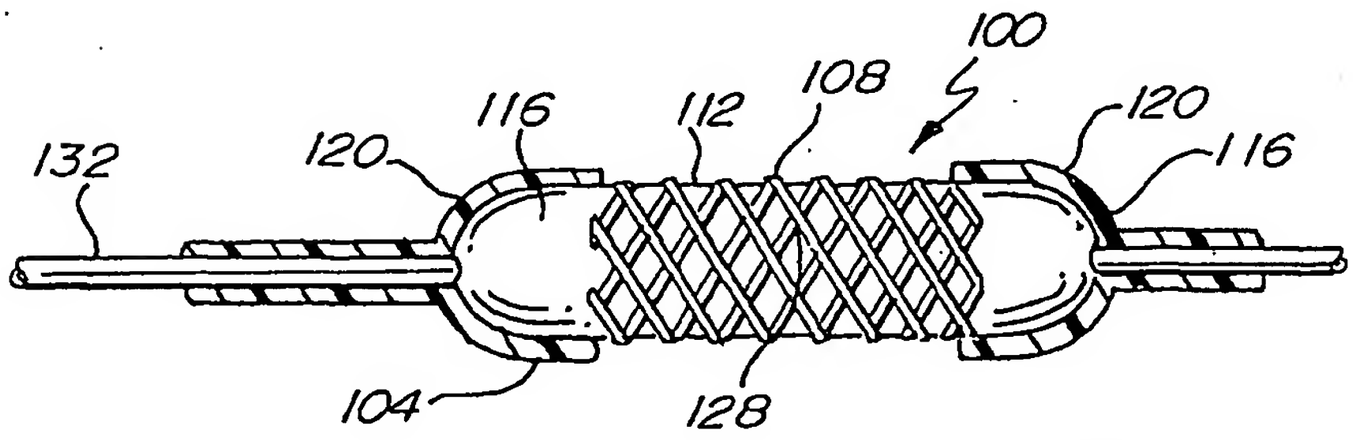


Fig. 4.

INTERNATIONAL SEARCH REPORT

	ıational Application No PCT/US 01/02010

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 403 341 A (SOLAR) 4 April 1995 (1995-04-04) abstract column 3, line 3 - line 20; figures 4A,C,5A-D	15,16, 18-24, 27,28 1-14,17, 25,26, 29,30
A	--- US 6 004 289 A (SAAB) 21 December 1999 (1999-12-21) abstract column 2, line 34 -column 3, line 10; claims 1,5,8-15; figures 5,7A-E	1,2,6-9, 15-17, 22, 25-27, 29,30
	--- -/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 July 2001	18/07/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Michels, N

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/02010

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 980 530 A (RANDBY ET AL.) 9 November 1999 (1999-11-09) abstract; figures 1,2	1-30
A	US 5 807 327 A (GREEN ET AL.) 15 September 1998 (1998-09-15)	
A	WO 97 32624 A (SCIMED LIFE SYSTEMS, INC.) 12 September 1997 (1997-09-12)	

INTERNATIONAL SEARCH REPORT

Information on patent family members

national Application No
PCT/US 01/02010

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5403341 A	04-04-1995	US 5549635 A	27-08-1996
US 6004289 A	21-12-1999	US 5755690 A	26-05-1998
		US 5358486 A	25-10-1994
		AU 7524391 A	21-11-1991
		DE 69123781 D	06-02-1997
		DE 69123781 T	15-05-1997
		EP 0457456 A	21-11-1991
		ES 2096625 T	16-03-1997
		IE 911648 A	20-11-1991
		JP 4231070 A	19-08-1992
US 5980530 A	09-11-1999	AU 4062297 A	06-03-1998
		EP 0932376 A	04-08-1999
		WO 9807388 A	26-02-1998
		US 6068634 A	30-05-2000
US 5807327 A	15-09-1998	AU 705164 B	20-05-1999
		AU 7413996 A	12-06-1997
		CA 2192295 A	09-06-1997
		EP 0778012 A	11-06-1997
		JP 9276414 A	28-10-1997
WO 9732624 A	12-09-1997	US 6124007 A	26-09-2000
		EP 0888145 A	07-01-1999